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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,468	10/23/2001	Fatemeh Mojtabai	FMI-001	4328

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LAHIVE & COCKFIELD, LLP.  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/003,468

Applicant(s)

MOJTABAI, FATEMEH

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6,8,55-58 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) 55-58 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,63-65,67 and 68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/17/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

Claims 55-58 and 66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/3/05. In the response filed 1/3/05, applicant elected species of proteoliposomes as the material used to apply the proteins at the interface. The species of liposomes and cellular membrane were nonelected species. Amended claim 55 newly recites applying a protein to an interface in a membrane preparation, and new claim 66 recites contacting a membrane preparation with an interface. Thus, claims 55-58 and 66 are directed to nonelected species, and are withdrawn.

An action on the merits of claims 1, 4-6, 8, 63-65, and 67-68, as they read on the elected species of membrane protein, proteoliposome, and gas-aqueous interface, follows.

***Information Disclosure Statement***

The IDS filed 11/17/05 has been considered in full.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 65 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 1, as amended, limits a 2D ordered array to have a diameter "greater than 25  $\mu\text{m}$ " and claim 65 limits the diameter to be "greater than 200  $\mu\text{m}$ ", both of which are new matter. The original claims did not recite any diameter limitations. Ordered structures In the response filed 9/30/05, applicant points to pages 55 and 14 for support for the recited ranges. However, page 55, at lines 30-31, teaches that ordered structures were 25-50  $\mu\text{m}$  in diameter. Page 14, lines 35-36 of the originally filed specification discloses ordered structures of 200-500  $\mu\text{m}$ , but does not disclose that this is a diameter. As the structures, especially 2D structures maybe linear, this measurement may, in fact, be a linear measurement. Nowhere does the originally filed specification specifically disclose an ordered structure with a diameter greater than 50  $\mu\text{m}$  or ANY structure with a measurement in any dimension between 50 and 200  $\mu\text{m}$  or greater than 500  $\mu\text{m}$ . Thus, the originally filed disclosure fails to provide support for the newly added limitations, and the claims are rejected for reciting new matter. Claims 4-6, 8 and 65 depend from claim 1 and are therefore also rejected for reciting new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 3-5, 8, 64, and 67-68 are rejected under 35 U.S.C. 102(b) as being anticipated by RIBI (US 4859538).

RIBI teaches a method of constructing 2 and 3 dimensional ordered (crystalline) arrays of proteins by contacting an air-water interface with a lipid composition comprising a protein, and allowing the mixture to incubate under spreading (i.e. lateral) pressure until the crystals (array) form (see examples at col. 12, col. 11, line 55-col. 12, line 8, and col. 12, line 50-col. 13, line 22). RIBI teaches that structures made by his method may be 1-25  $\mu\text{m}$  in diameter (col. 3, lines 25-40), thus claims 1, 3, 5, 8, and 67 are anticipated. RIBI teaches that a variety of proteins, including membrane proteins may be crystallized in his method (col. 4, lines 51-62 and col. 8, lines 42-50), thus claim 4 is anticipated. RIBI specifically teaches application of lateral pressure (col. 7, lines 31-37) and teaches that surfactants and polymers are not necessary to get ordered protein arrays, therefore the pressure applied is inherently above whatever critical density point is required for formation of a 2D or 3D ordered array, and claims 64 and 68 are anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over RIBI (US 4859538), as applied to claims 1, 3-5, 8, 64, and 67-68 above, and further in view of OHLSSON et al. (Bioelectrochemistry and Bioenergetics (1995) vol. 38, pp. 137-148).

RIBI teaches a method of obtaining 2D and 3D ordered/crystalline structures of proteins wherein proteins and lipids are exposed to pressure at an air/liquid interface, as set forth above. RIBI specifically teaches crystallization of cholera toxin subunit B (col. 12, line 50-col. 13, line 22). RIBI does not specifically teach use of proteoliposomes in his method.

OHLSSON teaches that cholera toxin may be bound to proteoliposomes on a surface, and will retain its activity when so bound (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to have used the proteoliposomes of OHLSSON in the lipid layer in the method of RIBI where the motivation would have been to crystallize the protein in the method of RIBI in an active conformation, as suggested by the teaching of OHLSSON that proteoliposomes aid in retaining biological activity of at least one membrane protein (abstract).

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
12/27/05